REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at (858) 720-5133.

Status of the Claims

Pending claims

Claims 1 to 4, 6 to 12, 14 to 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 93, 102 to 107 and 122 to 135 are pending and under consideration. Claims 74, 108, 112 to 116 and 118 to 121 remain withdrawn.

Claims added and canceled in the instant amendment

In the present response, claim 93 is canceled, without prejudice or disclaimer, and claims 136 to 166 are added. Thus, after entry of the instant amendment, claims 1 to 4, 6 to 12, 14 to 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 102 to 107 and 122 to 166 will be pending and under consideration.

Claims allowed and objected to

Applicants thank the Examiner for finding claims 2 to 4 are allowable; and, noting that claims 14, 15, 134 and 135 would be allowable if re-written to overcome the rejections under section 112, second paragraph (see new claims 143 to 146).

Restriction Requirement and Rejoining process claims

In response to the Restriction Requirement mailed May 22, 2003, Applicants elected Group 62, for the nucleic acid having a sequence as set forth in SEQ ID NO:125, vectors, host cells, probes and a method of making the encoded polypeptide (SEQ ID NO:126), with traverse and argument. As noted in their response of February 24, 2004, Applicants respectfully requested that, after the elected product claims have been found to be allowable, all withdrawn process (methods) claims which depend from or otherwise include all of the limitations of the allowed product claims be rejoined.

Outstanding Rejections

Claims 12, 14 to 17, 48, 102 to 107, 128, 129, 134 and 135 are rejected under 35 U.S.C. §112, second paragraph. The rejection of claims 10 to 12, 17, 48, 75 to 80, 84 to 86, 88, 89, 92, 93 and 102 to 107, is maintained, and claims 128, 129 and 131 to 133 are newly rejected under 35 U.S.C. §112, first paragraph, written description requirement. The rejection of claims 1 to 18, 47, 48, 74 to 89, 92, 93 and 102 to 108, 112 to 116 and 118 to 120 are rejected under 35 U.S.C. §112, first paragraph, is maintained because the specification allegedly does not reasonably provide enablement for the claimed invention (enablement requirement). The rejection of claims 10, 11, 48, 75, 76, 84 to 86, 92, 102 to 107, is maintained under 35 U.S.C. §102(b) under 35 U.S.C. §102(b) as allegedly anticipated by Tachibana et al. (Database GenBank, US National Library of Medicine (Bethesda, MD, USA), No. D83793, TACHIBANA et al., 01 February 2000) ("Tachibana"). The rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art has been maintained.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for Claim Amendments

Support for the new and amended claims can be found throughout the application for the skilled artisan. For example, support for claims directed to nucleic acids and polypeptides of the invention of various lengths and identities can be found, inter alia, in paragraph 74, page 17; paragraphs 201 to 203, pages 50 to 51; paragraphs 237-239, pages 60-61; paragraphs 251-252, pages 64-66, of the specification. Support for claims directed to using the nucleic acids of the invention to produce a feed can be found, e.g., in paragraph [0003] of page 1. Support for claims directed to methods for hydrolyzing a starch linkage or catalyzing the breakdown of a starch using the nucleic acids of the invention can be found, inter alia, in paragraphs [0054], [0056] and [0057], pages 11 to 12. Support for claims directed to methods for making an alcohol using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraph [0051], page 10. Support for claims directed to methods comprising a corn wet milling process using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraph [0051], page 10. Support for claims directed to methods comprising a baking

process, a brewing process or a drilling process using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraphs [0003] and [0051], pages 1 and 10. Support for claims directed to methods of textile processing using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraphs [0003], [0013] and [0051], pages 1, 4 and 10. Support for claims directed to methods of paper or pulp processing using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraphs [0003], [0013] and [0051], pages 1, 4 and 10. Support for claims directed to methods of making beverages using the nucleic acids of the invention can be found, inter alia, in paragraph can be found, inter alia, in paragraphs [0003] and [0051], pages 1 and 10.

Accordingly, Applicants submit that no new matter is introduced by the present amendments.

Claim Objections

Claim 48 is objected to under 37 CFR 1.75(c); see page 2, lines 18 to 20, of the OA. The instant amendment addresses these issues.

Issues under 35 U.S.C. §112, second paragraph

Claims 12, 14 to 17, 48, 102 to 107, 128, 129, 134 and 135 are rejected under 35 U.S.C. §112, second paragraph 7 to 9 stand rejected under 35 U.S.C. §112, second paragraph, for reasons set forth in the paragraphs of line 21, page 2 to line 21, to page 4, line 10, of the OA. The instant amendment addresses this issue.

Issues under 35 U.S.C. §112, first paragraph

Written Description

The rejection of claims 10 to 12, 17, 48, 75 to 80, 84 to 86, 88, 89, 92, 93 and 102 to 107, is maintained, and claims 128, 129 and 131 to 133 are newly rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention, for reasons set forth in the OA from page 4, line 11, to page 8, line 11, of the OA. The instant amendment addresses these issues.

For example, the Office was concerned that in some of these claims recited structural features were not correlated with recited functional features (see, e.g., page 5, lines 15 to 19, of the OA). The instant amendment endeavors to correct this possible problem, e.g., see amended claim 10, now drawn to nucleic acids comprising, inter alia, a sequence encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 98% sequence identity to 150 consecutive amino acid residues of SEQ ID NO:126.

The Office remains concerned that some of these claims may have no functional limitation (see, e.g., page 6, lines 1 to 4, of the OA). The instant amendment endeavors to address this issue; e.g., as in claim 17, where the amendment clarifies that the claimed probe can hybridize to an amylase-encoding gene under the enumerated stringent conditions. While Applicants acknowledge that all species members of a genus of biological sequences must have a structure-function relationship, they respectfully aver that the linking functional limitation of the members of the genus does not necessary have to be its natural biological function, but can be another function, e.g., as a research tool, for example, a probe to isolate or identify a protein-encoding sequence. Thus, for example, claim 75 (as amended), is drawn to nucleic acid probes for identifying or isolating an amylase-encoding gene (where the probes comprise, inter alia, an oligonucleotide consisting of at least about 50 contiguous nucleotides a sequence of claim 2). Similarly, claim 128 (as amended) is drawn to probes comprising a nucleic acid having at least 85% sequence identity to SEQ ID NO:125, wherein the probe can identify or isolate an amylase-encoding gene.

The Office also remains concerned that some of these claims recite only structural features (see, e.g., page 6, lines 4 to 9, of the OA). The instant amendment endeavors to address this issue; e.g., as in claim 10, as amended, is drawn to nucleic acids comprising a sequence encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 98% sequence identity to 150 consecutive amino acid residues of SEQ ID NO:126; thus all species of the genus of claim 10 have a functional limitation that correlates with a defined structure.

Enablement

The rejection of claims 1, 6 to 12, 16, 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 93 and 102 to 107, is maintained, and claims 122 to 133 are newly rejected under 35 U.S.C. §112, first

paragraph, because the specification allegedly does not reasonably provide enablement for the claimed invention, for reasons set forth in the OA from page 8, line 12, to page 15, line 2.

The Patent Office through its allowance of claim 2 to 4 has acknowledged that the specification is enabling for a genus of nucleic acids, e.g., as in claim 3, encoding a polypeptide having alpha amylase activity that hybridizes under stringent conditions to a sequence selected from the group consisting of: (a) a sequence as set forth in SEQ ID NO:125; (b) a sequence encoding a polypeptide having a sequence as set forth in SEQ ID NO:126; and, (c) sequences complementary to (a) or (b); where specific stringent conditions are included.

Applicants respectfully aver that the specification enabled the skilled artisan at the time of the invention to identify, and make and use, the claimed genera of amylase-encoding nucleic acids, e.g., as in claim 1, drawn to, inter alia, nucleic acids comprising a sequence encoding a polypeptide having alpha amylase activity, wherein the sequence has at least 85% sequence identity to a sequence as set forth in SEQ ID NO:125, or a sequence encoding a polypeptide having alpha amylase activity, wherein the sequence has at least 90% sequence identity to a sequence as set forth in SEQ ID NO:126.

Applicants have provided sufficient evidence and expert declaration to support this argument, as set forth in their previous responses, e.g., of April 05, 2005; August 20, 2004; and, February 24, 2004, which are expressly incorporated herein.

Because Applicants' previous responses are expressly incorporated herein, they will not be reiterated in this submission. However, because one of the Office's concerns is that it would have taken undue experimentation to make the genus of template polypeptides used to practice this invention, Applicants believe a brief review of the standard used in determining undue experimentation as set forth in In re Wands would be helpful:

Applicants have maintained that the specification provided reasonable enablement regarding the structure and sequence of the genera of claimed nucleic acids. Whether large numbers of compositions (e.g., a genus of amylase-encoding nucleic acids) must be screened to determine if one can be used to practice the claimed invention is irrelevant to an enablement inquiry. Enablement is not precluded by the necessity to screen large numbers of compositions, as long as that screening is "routine," i.e., not "undue," to use the words of the Federal Circuit. The Federal Circuit in In re

Wands directed that the focus of the enablement inquiry should be whether the experimentation needed to practice the invention is or is not "undue" experimentation. Guidance as to how much experimentation may be needed and still not be "undue" was set forth by the Federal Circuit in, e.g. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987), which was discussed in Applicants' response of July 17, 2003.

The proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). See MPEP §2164.08, pg 2100-205, 206, 8th ed., rev. 3, Aug. 2005. `The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' " In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). MPEP §2164.06(b), pg 2100-203, 8th ed., rev. 3, Aug. 2005.

The facts in In re Wands are sufficiently analogous to the instant application to help illustrate this point, as explained in the MPEP (§2164.06(b), pg 2100-203, 8th ed., rev. 3, Aug. 2005):

> (B) In In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

In In re Wands, after considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed

invention." Id., 8 USPQ2d at 1407. In In re Wands, it was not necessary to provide a method to routinely identify *every* monoclonal antibody hybridoma made in any particular production round, or *every possible* monoclonal antibody that could bind the exemplary antigen. Nor was it necessary to produce a working specie after very antibody-making procedure. In fact, in In re Wands, the screening protocol was found sufficiently enabling even though only one antibody was identified after running three procedures.

Analogous to In re Wands, it is not necessary that the specification or the state of the art at the time of the invention describe a protocol where every, or even most, attempts at making a template nucleic acid (within the limitations of the claimed invention) are successful. Because proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims, as in In re Wands, methods for making the claimed genera of amylase-encoding nucleic acids are sufficiently enabling if a reasonable number of species are successfully made by protocols known in the art and/or described in the specification. Protocols for amylase activity screening were well known in the art at the time of the invention; see e.g., Example 2, pages 84 to 86; Example 5, pages 87 to 89; Example 6, pages 90 to 93; Example 7, pages 94 to 103; Example 9, page 105, of the specification.

Thus, using the teaching of the specification and other protocols known in the art at the time of the invention one skilled in the art could have successfully practiced the invention without undue experimentation, including making and using the claimed genus of amylase-encoding nucleic acids without undue experimentation. In other words, methods for making and screening for amylases were sufficiently sophisticated and well known at the time of the invention that one of skill in the art could have made the genus of template nucleic acids used in the claim methods without "undue experimentation", according to the appropriate legal definition of this term, e.g., as in In re Wands.

Furthermore, also analogous to In re Wands, because the specification provided direction and guidance on how to practice the claimed invention and all of the methods needed to practice the invention were well known, and there was a high level of skill in the art at the time the application was filed, the instant specification did provide reasonable enablement commensurate with the scope of the claimed invention. Accordingly, the enablement rejection under section 112, first paragraph, can be properly withdrawn.

In light of the above remarks and the present claim amendments, Applicants respectfully submit that amended claims are fully enabled by and described in the specification to overcome the rejection based upon 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §102(b)

The rejection of claims 10, 11, 48, 75, 76, 84 to 86, 92, 102 to 107, under 35 U.S.C. §102(b) as allegedly anticipated by Tachibana et al. (Database GenBank, US National Library of Medicine (Bethesda, MD, USA), No. D83793, 01 February 2000) is maintained (just a note: Tachibana was reference "AQ", not "AK" in the IDS of September 29, 2003).

The Office alleged that Tachibana has greater than 95% identity over 75 nucleotides to this invention's SEQ ID NO:125 (residues 1463-1537 of Tachibana vs. residues 1018-1092 of SEQ ID NO:125). This is incorrect, please see the attached sequence alignment (Tachibana vs. SEQ ID NO:125) – there are 5 mismatches over 75 residues, making Tachibana 93.3% identity over 75 residues.

The instant amendment also addresses this issue; for example, claim 10 as amended is directed to a genera of nucleic acids comprising, inter alia, a sequence encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 98% sequence identity to 150 consecutive amino acid residues of SEQ ID NO:126; and claim 11 as amended is directed to nucleic acid comprising a genera of nucleic acids comprising, inter alia, sequences encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 99% sequence identity to 100 consecutive amino acid residues of SEQ ID NO:126.

In light of the instant amendment, Tachibana does not teach all of the elements of the amended claims. Accordingly, because Tachibana is not a single reference teaching each and every element of the claimed invention, withdrawal of the rejection under section §102 is respectfully requested.

Issues under 35 U.S.C. §103(a)

The rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art has been maintained.

As discussed above, the instant amendment removes Tachibana as a single reference teaching each and every element of the claimed invention. The state of the art at the time of the invention does not cure the defect in Tachibana to teach the claimed (amended) sequences. Accordingly, the rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art can be withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 564462006100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at (858) 720-5133.

Dated: June 29, 2006

Respectfully submitted,

By _____

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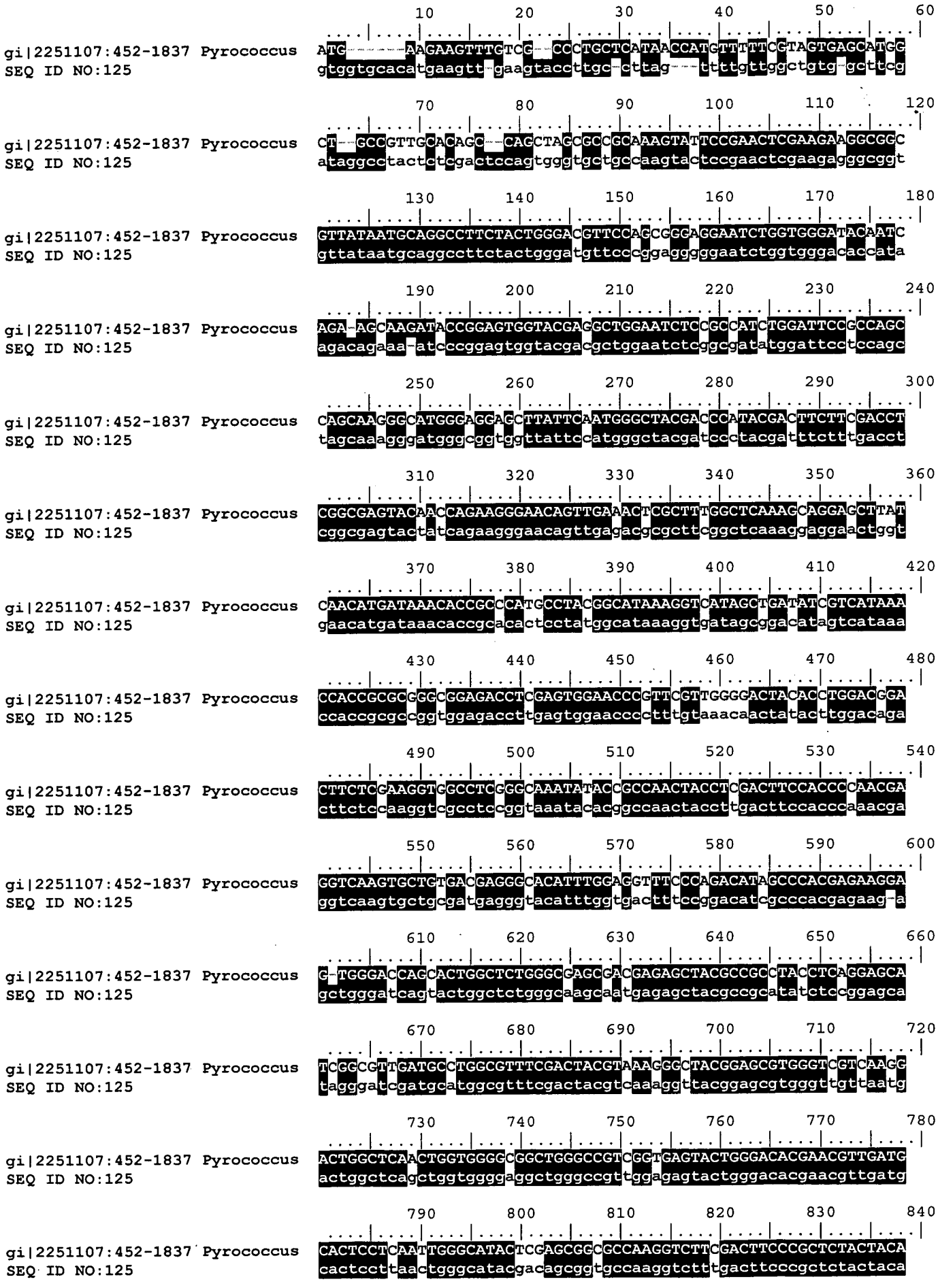
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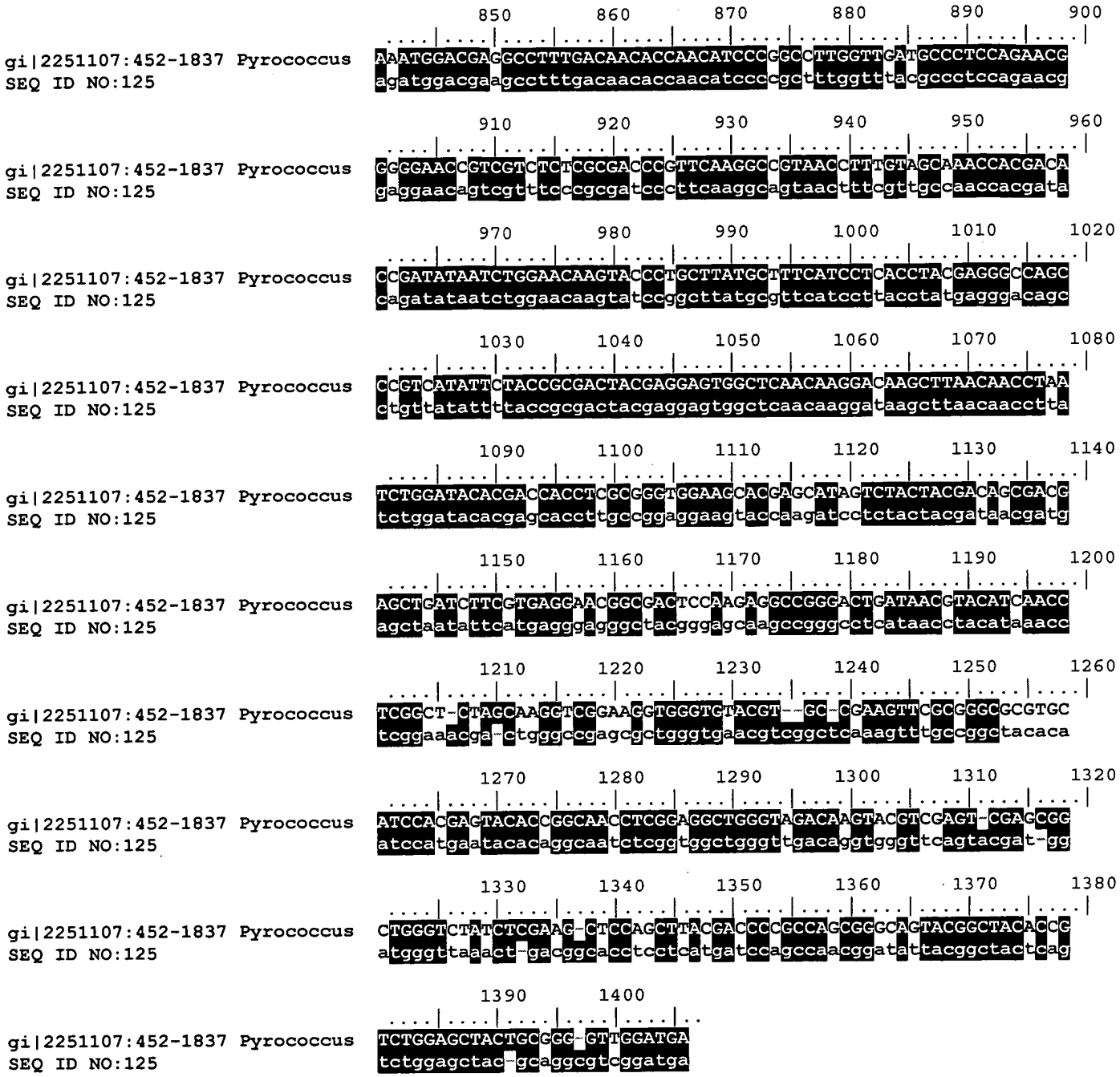
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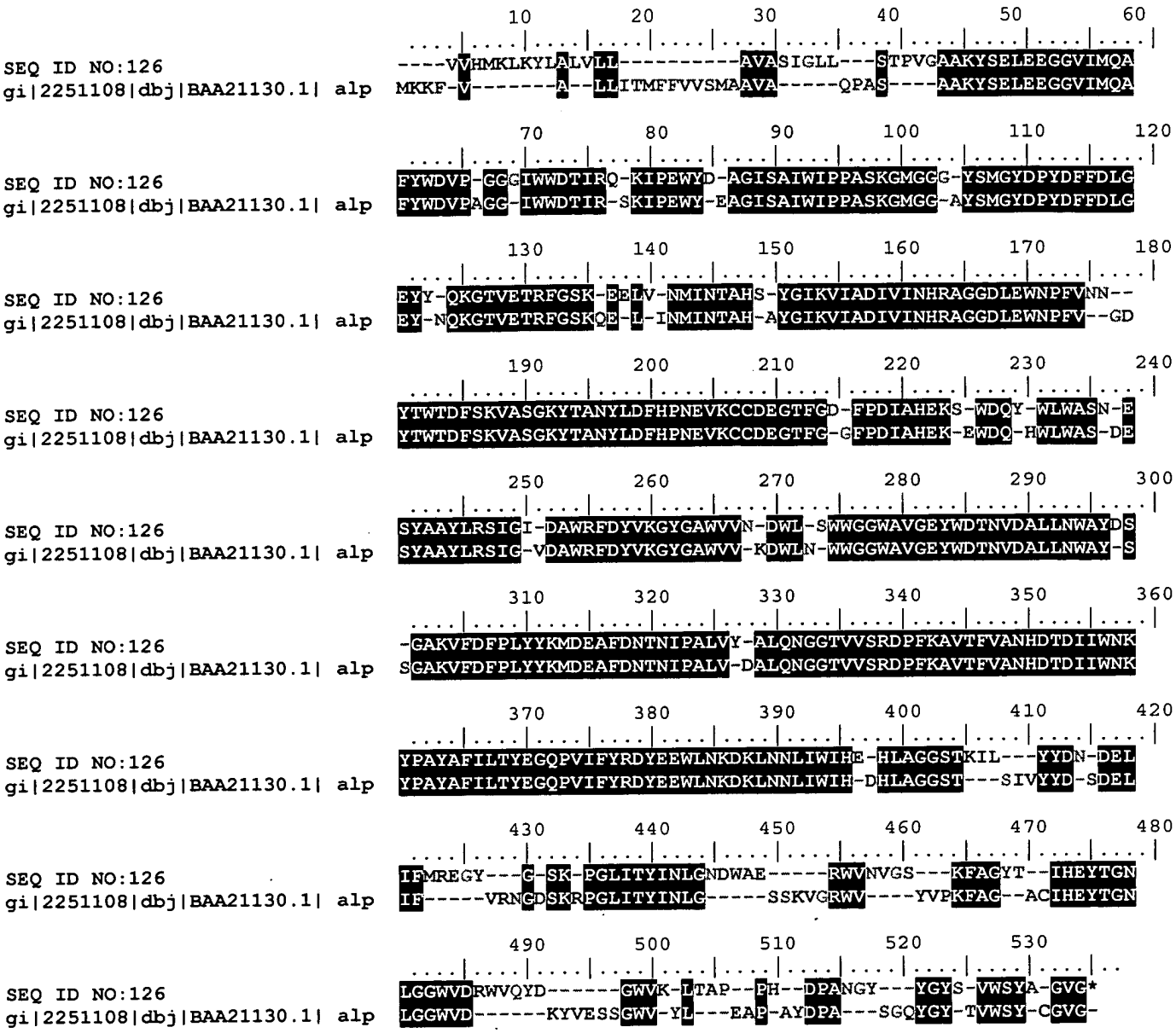
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